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Via ECF & Hand Delivery

The Honorable Sherry R. Fallon
United States District Court for the District of Delaware
844 North King Street
Wilmington, Delaware 19801

Re: *Allergan, Inc. v. Taro Pharm. Indus. Ltd.*, No. 17-663-VAC-SRF (Consolidated)

Dear Judge Fallon,

Taro Pharmaceutical Industries Ltd. and Taro Pharmaceuticals, Inc. (collectively “Taro”) submit this responsive letter regarding the parties’ dispute relating to the proposed Protective Order in the above case. The parties seek assistance from the Court in resolving their disputes regarding each party’s right to determine the appropriate confidentiality designation of their own documents as well as determining the appropriateness of a member of an in-house Intellectual Property Group having access to the Confidential information of the opposing party.

I. Each Party Has the Burden, Responsibility and Right to Determine and Justify the Confidentiality Designations of Its Own Documents

Allergan proposed and the parties agreed to a two-tiered Protective Order (Confidential and Highly Confidential) whereby the in-house representatives designated in the Protective Order would only have access to Confidential, not Highly Confidential information. Based on this two-tiered Protective Order, it is understood the parties agree there are documents and information too sensitive to be reviewed by an in-house representative. While Allergan may disagree, Taro’s position is its ANDA is Highly Confidential. Taro believes, as the Designating Party, it (and not Allergan, the “Non-Designating Party”)¹ is entitled to designate Taro’s ANDA (and Taro’s other documents) as it deems appropriate. Paragraph 1 of the draft Protective Order states:

This Protective Order applies to any document, or portion thereof, any type of information, including electronically stored information and any form of discovery contemplated under Rules 26 through 36 of the Federal Rules of Civil Procedure that, **in the good-faith opinion of the party providing such material (the “Producing Party” or “Designating Party”),** contains any trade secret or other confidential research, development, manufacture, regulatory, financial, marketing or other competitive information of the Producing Party, or a nonparty if such documents and information are within the possession, custody or control of the Producing Party. **The party receiving such information is herein referred to as the “Receiving Party” or “Non- Designating Party.”** This

¹ See D.I. 34 at Ex. A, Paragraph 1.

Protective Order describes the information protected under its terms and the use and disclosure of such protected information.

See D.I. 34, Ex. 1 at Paragraph 1 (emphasis added). As noted, the draft Protective Order allows each party to designate its own documents. If the Receiving Party disagrees with any designation, there is a protocol in the draft Protective Order for resolving that dispute. *Id.* at §V. The cases cited by Allergan and included in its exhibits focus on instances where one party or both parties requested that an in-house representative have access to all materials. *See, e.g.*, D.I. 34 at Exs. D and E; *Avery Dennison Corp. v. Minn. Mining & Mfg. Co.*, No. 01-125-JJF, 2001 WL 1339402, at *2 (D. Del. Oct. 26, 2001). But that is not the case here.² Here, Allergan proposed a second-tier of confidentiality in the draft Protective Order, recognizing in-house representatives should not have access to all litigation documents, but it now wishes to restrict Taro's rights to utilize that designation. Allergan is attempting to put itself in the position of the "Designating Party" and the "Non-Designating Party" of Taro's documents. This position is contrary to the Federal Rules and established case law regarding the burden of designation.³

A. Taro's Offers of Compromise to Allow Designated In-House Counsel Access to Certain Highly Confidential Documents

As continually expressed throughout the negotiations regarding the Protective Order, Taro is willing to, and will, designate certain formulation information in Taro's ANDA as being Confidential solely for the purpose of allowing Allergan's designated in-house counsel access. Taro has also expressed its willingness to consider granting designated in-house counsel access to other sections of Taro's ANDA Allergan requests. Despite having had access to Taro's ANDA since August 1, 2017, Allergan has refused to explicitly identify the sections it wishes to share with in-house counsel, only delaying designated in-house counsel's access to certain of Taro's ANDA documents. On September 22, 2017, Allergan represented it was going to provide certain sections of Taro's ANDA to its experts and in-house counsel. *See* Ex. A, Sept. 22, 2017 email from E. Andersen identifying eight sections of Taro's ANDA. Taro objected to this as the parties had not yet agreed to a form of protective order nor had one been entered by the Court.⁴ *Id.*,

² In its November 1, 2017 letter (D.I. 34), Allergan offers to the Court an alternative single-tier confidentiality provision, thereby removing both parties' rights to protect their Highly Confidential information. Taro does not agree that a single-tier Protective Order is appropriate.

³ Having the burden of justifying a confidentiality designation presupposes the same party first designated the document. *See United States v. Wecht*, 484 F.3d 194, 211 (3d Cir. 2007) ("[T]he burden of justifying the confidentiality of each and every document sought to be covered by a protective order remains on the party seeking the protective order.")

⁴ While Allergan again attempts to paint Taro as "delaying" access and review of Taro's ANDA, it should be noted, under the Scheduling Order, Taro was not required to produce its ANDA until October 20, 2017. *See* D.I. 26. Instead, Taro produced its ANDA, pursuant to D. Del. Local Rules 26.2 to Allergan's outside counsel of record, on August 1, 2017. On September 29, 2017, Taro also agreed to grant Allergan's experts access to the entire ANDA, as long as the procedures in the draft protective order were followed. *See* Ex. B, Sept. 29, 2017, email from S. Benson. Despite its repeated protestations of Taro hindering its ability to review the ANDA,

Sept. 22, 2017 email from S. Benson. At a meet-and-confer on September 28, 2017, Taro expressed its willingness to confer with its client regarding allowing access to the sections identified in Allergan's email. However, Allergan's counsel refused, stating its position was that designated in-house counsel was entitled to access Taro's entire ANDA, or that Taro should be telling Allergan which documents it will or will not allow Allergan's counsel to access, despite Taro's position that the entire ANDA is Highly Confidential. *See* Ex. B, Sept. 28 and 29, 2017, emails between S. Benson and E. Andersen. Once a Protective Order is in place, Taro will designate portions of its ANDA as Confidential, exactly as it has always stated it would do. *Id.*

Allergan attempts to argue Taro is shifting the burden of making confidentiality designations to Allergan by offering to compromise. Allergan is incorrect. Instead, Allergan is attempting to restrict Taro's right to designate its own documents. Taro has made the determination its ANDA is Highly Confidential. Taro is attempting to work with Allergan to provide its designated in-house counsel with the specific materials Allergan believes its designated in-house representatives need to review. Despite Allergan's claims, this procedure would in no way reveal what Allergan's outside counsel intends to discuss with designated in-house counsel (only what designated in-house counsel has access to), and is contrary to Allergan's prior attempt to provide Highly Confidential information to its in-house counsel in September (a request it has since withdrawn). *See* Ex. B, Sept. 29 email from E. Andersen at 4:04pm. Further, Allergan's outside counsel has always been free to follow the procedures for reviewing and discussing information designated as Highly Confidential with its in-house counsel.

B. Taro Should be Allowed to Designate Its Own Documents and Protect Its Sensitive Information

As noted in Taro's Motion for Leave to file Summary Judgment, Allergan has no basis to maintain this lawsuit, as Taro does not infringe the patent-in-suit. D.I. 24. Given Taro's position regarding infringement and Allergan's continued prosecution of related patents, Taro does not believe Allergan's in-house counsel should be entitled to review Taro's entire ANDA, and a Highly Confidential designation for Taro's ANDA is uniquely appropriate. Taro's ANDA contains highly sensitive information, which Allergan's in-house counsel does not need to access in order to assist in this litigation. As noted above, Allergan's outside counsel has had access to the entire ANDA since August 1, 2017. Taro expects Allergan's counsel is fully capable of reviewing Taro's ANDA and providing advice and analysis based on its review to Allergan's in-house counsel for the purposes of this litigation. Any prior agreements by Taro to enter into a Protective Order allowing different access to materials would have been a determination made specifically on the unique facts surrounding that matter. Prior agreements entered into by Taro have no bearing on Taro's position in this litigation.

While Allergan has attempted to identify what categories of documents can and cannot be designated as Confidential or Highly Confidential, it is not Allergan's place to make a determination as to how Taro designates its own documents, nor should Taro determine the confidentiality designations for any of Allergan's documents. As repeatedly pointed out by

Allergan did not provide the signed Exhibits or CVs until October 11, 2017. *See* Ex. C, email from M. Wallace.

Allergan, it is the Designating Party's burden to justify its confidentiality designations. As required under the Federal Rules, Taro will review its documents to determine the appropriate confidentiality designation for each document. Under the draft Protective Order, Allergan has the right to challenge any such designation. At the very least, Allergan's disagreement is premature as Taro has already committed to designate certain portions of the ANDA as Confidential.

II. Taro Should Be Allowed to Designate a Member of its Intellectual Property Group as an Individual to Receive Confidential Information

Until Allergan's correspondence to the Court on November 1, 2017, Taro was unaware Allergan had an objection to Taro's second designated representative being located outside of the United States. Taro informed Allergan on October 6, 2017, during a meet-and-confer, the second representative would likely be located in India. At no time has Allergan asked whether or not a designated representative would agree to be subject to the Court's jurisdiction for purposes of enforcing the Protective Order, or expressed concern that person would not be. Taro affirmatively represents that any representative designated under the Protective Order to receive Confidential Information will agree to be bound by the terms of the Protective Order and agree to be subject to the Court's jurisdiction for the purpose of enforcing the Protective Order.

Allergan has not pointed to any support for its position that Taro should not be permitted to designate an individual from its Intellectual Property Group responsible for managing and counseling litigation, as a person to have access to Confidential information under the Protective Order. Nor has it pointed to any reason to believe any improper use would somehow be more likely with a non-attorney representative than it would be with any other in-house legal representative. A primary consideration in whether to permit in-house representatives to access an opposing party's confidential information is whether that representative is involved in competitive decision making. *See, e.g., US. Steel Corp. v. United States*, 730 F.2d 1465, 1468–69 (Fed. Cir. 1984). In *US. Steel*, the Federal Circuit set forth a standard focused on the representative's activities-not the representative's title or country of residency. *Id.* "Thus the factual circumstances surrounding each individual counsel's *activities, association, and relationship* with a party ... must govern any concern for inadvertent or accidental disclosure." *Id.* at 1468 (emphasis added). Taro has informed Allergan that the individual it would designate would be in a counseling role in relation to the litigation and would also be working at the direction of in-house counsel.⁵ Neither the title nor geographical location of Taro's representative are of any consequence. *See Ex. E, Iceutica Pty. Ltd. v. Lupin*, 14-cv-1515-SLR-SRF, June 15, 2015, Tr. at 40:14-42:19, 43:11-22 (Defendant wished to name an in-house representative who was not a lawyer and resided in India as an individual to receive confidential information. This Court granted the request noting the individual must sign the protective order and be subject to the Court's jurisdiction for enforcement of the protective order).

Taro respectfully requests the Court allow it to designate a non-attorney member of its Intellectual Property Group, whose responsibilities are focused on the management of litigation, as a person to have access to Confidential information under the Protective Order.

⁵ *See Ex. D*, Oct. 24, 2017, email from K. Beis. Allergan provided no response to this email.

Respectfully submitted,

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (No. 110)

cc: All counsel of record (via CM/ECF & email)